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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,548	10/18/2001	Dongfang Liu	M0656/7070(HCL)	7782
23628	7590	08/08/2006	EXAMINER	
WOLF GREENFIELD & SACKS, PC FEDERAL RESERVE PLAZA 600 ATLANTIC AVENUE BOSTON, MA 02210-2206			MCINTOSH III, TRAVISS C	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/982,548

**Applicant(s)**

LIU ET AL.

**Examiner**

Traviss C. McIntosh

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 43,58,116-121,204,206-209,211-213 and 223-234 is/are pending in the application.
- 4a) Of the above claim(s) 233 and 234 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 43,58,116-121,204,206-209,211-213 and 223-232 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Group II in the reply filed on 5/5/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

It is noted that newly added claims 233-234 have been withdrawn as being drawn to a non-elected group. Claims 233-234 are drawn to methods further comprising administering an additional therapeutic agent. However, "combination therapy" was restricted away from the elected group (see restriction groups VI, VII, and VIII), which applicant elected the unformulated group without traverse.

Claims 204, 206-208, and 211-213 have been amended.

Claims 223-234 have been added

Claims 1-42, 44-57, 59-115, 122-203, 205, 210, and 214-222 have been canceled.

Remarks drawn to rejections of Office Action mailed 2/25/2005 include:

Specification Objection: which has been overcome by applicant's amendments and has been withdrawn.

112 1<sup>st</sup> paragraph rejection: which has been overcome by applicant's amendments and has been withdrawn.

112 2<sup>nd</sup> paragraph rejections: which have been overcome in part by applicant's amendments and have been withdrawn in part.

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102(b) rejection: which has been withdrawn due to applicants arguments, specifically, that Illum et al. does not teach using unformulated particles.

An action on the merits of claims 43, 58, 116-121, 204, 206-209, 211-213, and 223-232 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

Claims 43, 58, 116-120, 204, 206-209, 211-213, and 223-232 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase “heparin-like glycosaminoglycan” in every claim which is silent to how the molecule must be like heparin, is a relative term which renders the claims indefinite, and therefore the rejection is maintained for reasons of record. The term is not defined by the claims, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. How must another compound be like heparin to be considered “heparin-like”? Must it have the same properties, be the same size, have the same functional groups, comprise the same linking groups?

Applicants argue that the term “heparin-like glycosaminoglycan” (HLGAG) has been used since 1969 and a search in the PubMed database produced 23 different articles using the term. Applicants then state that this alone shows the term was known and understood by those in the art. Applicants then provided a reference which comprises a definition of HLGAG, which is presumed by applicants to show that there was an understanding in the art of what the compound

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was. According to the reference provided, Rhomberg et al. state that HLGAG is a complex polysaccharide characterized by a disaccharide repeating unit of an uronic acid which is 1-4 linked to a glucosamine. However, it is noted that upon review of the art, this is not seen to be the universal definition for HLGAG, as US 7,056,504 states that HLGAGs are characterized by a disaccharide repeating unit of uronic acid and which is 1-4 linked to a hexosamine (see column 1, lines 20-30). The definition of Rhomberg and the '504 patent are seen to be different for HLGAGs, thus evidencing that one of skill in the art would not know the metes and bounds of the instant claims. Rhomberg states HLGAGs comprise glucosamine, however, the '504 patent states HLGAGs comprise a hexosamine, which is not of the same scope as glucosamine, as hexosamines can be galactosamine, mannosamine, etc. Stating what the actual compounds are in the claims, as in claim 121, not what they are like, would be seen to obviate the instant rejection.

Claim 232 is indefinite wherein the claim is drawn to a method of producing a therapeutic effect, but fails to state what is actually being affected. If applicants are claiming a method of treating a disease, applicants should include the diseases intended to be treated in the claims. The claim is indefinite where the claim fails to state the function which is to be effected therapeutically.

All claims which depend from an indefinite claim are also indefinite. *Ex parte Cordova, 10 U.S.P.Q. 2d 1949, 1952 (P.T.O. Bd. App. 1989).*

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 43, 116-119, 121, 204, 206-207, and 223-231 are rejected under 35 U.S.C. 102(e) as being anticipated by Gombotz et al. (US Patent 6,569,458 B1).

The claims of the instant application are drawn to unformulated HLGAGs, which is optionally heparin, having various diameters including ranges of 1-10  $\mu\text{m}$ .

Gombotz et al. disclose a method of making heparin particles having a diameter of 6.9+/- 4.0  $\mu\text{m}$  (thus providing a range of 2.9-10.9  $\mu\text{m}$ ), see example 5. These particles are seen to be unformulated as they do not contain any other agents. As such, Gombotz et al. is seen to teach the unformulated heparin particles having diameters that fall within the range of 2.9-10.9  $\mu\text{m}$  as claimed in the instant application.

***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Traviss C. McIntosh III  
August 4, 2006  
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A handwritten signature in black ink, appearing to read 'Traviss C. McIntosh III', written over a horizontal line.